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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,422	02/03/2000	Stephen A. Berry	ARC2914 US R1 (3139-6169U)	7482
7590	04/29/2005		EXAMINER	
Edgar R. Cataxinos TraskBritt, PC PO Box 2550 Salt Lake City, UT 84110			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/497,422	BERRY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 January 2005.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 10,11,15-18,21-23,27,29-32,35-38 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10,11,15-18,21-23,27,29-32,35-38 and 46-48 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/24/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

Examiner acknowledges receipt of supplemental IDS filed 01/24/05, and amendment and remarks filed 01/31/05. Claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38 and 46-48 are pending.

### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38, 46 and 47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is not maintained in light of the amendment to the claims.

### ***Claim Rejections - 35 USC § 102***

2. The rejection of claims 10, 11, 15-17, 21-23, 27, 46 and 47 under 35 U.S.C. 102(b) as being anticipated by Daher et al. (US 4,376,118) is withdrawn because the claims as amended now require the composition/vehicle to comprise a polymer that comprises polyvinylpyrrolidone, a surfactant that comprises glycerol monolaurate, and a solvent that comprises lauryl lactate; the composition/vehicle has a viscosity of between 1,000 and 10,000,000 poise and Daher's tetracycline containing vehicle does not contain polyvinylpyrrolidone.

3. The rejection of claims 10, 11, 15, 16, 46 and 47 under 35 U.S.C. 102(e) as being anticipated by Lyle (US 5,814,323) is withdrawn because the claims as amended now require the composition/vehicle to comprise a polymer that comprises polyvinylpyrrolidone, a surfactant that comprises glycerol monolaurate, and a solvent that comprises lauryl lactate; the composition/vehicle has a viscosity of between 1,000 and 10,000,000 poise and Lyle's vehicle/composition does not contain all three components of polyvinylpyrrolidone, glycerol monolaurate and lauryl lactate.

4. The rejection of claims 10, 11, 15-18, 21-23, 27, 35, 46 and 47 under 35 U.S.C. 102(e) as being anticipated by Farinas et al. (US 5,928,666) is withdrawn because the claims as amended now require the composition/vehicle to comprise a polymer that comprises polyvinylpyrrolidone, a surfactant that comprises glycerol monolaurate, and a solvent that comprises lauryl lactate; the composition/vehicle has a viscosity of between 1,000 and 10,000,000 poise and Farinas' vehicle/composition does not contain all three components of polyvinylpyrrolidone, glycerol monolaurate and lauryl lactate.

***Response to Arguments***

5. Applicants' arguments, see remarks/arguments, filed 01/31/05, with respect to the rejection(s) over Lyle, Farinas and Daher have been fully considered and are persuasive in light of the amendment. Therefore, the rejection has been withdrawn above. However, upon further consideration, a new ground(s) of rejection is made in over Daher et al. (US 4,376,118) and Yajima et al. (UD 5,972,373).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) and Yajima et al. (US 5,972,373).

Daher discloses non-aqueous solution of tetracycline that comprises N-methyl-2-pyrrolidone, lauryl lactate, antioxidant, polysorbate solubilizer (abstract, column 1, lines 52 and

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58; column 2, lines 6-12). The tetracycline composition of Daher does not contain polyvinylpyrrolidone. But, Yajima discloses a composition that contains tetracycline (column 2, lines 42 and 43), glycerol monolaurate or glycerol monostearate (column 2, lines 49-53), excipients (column 3, lines 19-29), disintegrants (column 3, lines 30-34), polyvinylpyrrolidone (column 3, line 38), antioxidant (column 3, lines 41-45), cellulose materials and dyes (column 3, lines 49-60) and polysorbate or polyoxyethylene-polyoxypropylene block copolymers (column 3, lines 61-65). The compositions of Daher and Yajima individually contains tetracycline antibiotic. “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The viscosity recited is a property of the composition. There does not appear to be demonstration that the viscosity provides unusual results to the recited composition. And a composition/vehicle comprising polyvinylpyrrolidone, lauryl lactate and glycerol monolaurate or polysorbate would necessarily have the recited viscosity and there is no demonstration in applicants’ disclosure that the viscosity conveys special results/effects to the composition. In the absence of a showing, the recited viscosity is not critical to a composition/vehicle that comprises polyvinylpyrrolidone, polysorbate or glycerol monolaurate, and lauryl lactate.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Daher and Yajima to form a third composition. One having ordinary skill in the art would have been motivated to combine the separate compositions of Daher and Yajima to form a third composition comprising tetracycline

antibiotic, polyvinylpyrrolidone, polysorbate, lauryl lactate, glycerol monolaurate and excipients and antioxidants with the expectation that the third composition would be useful as an antibiotic composition (In re Kerkhoven). The comprising language of the claims allows for the presence of other ingredients in the composition of the cited prior art.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The previously cited art, Farinas et al. (US 5,928,666), Lyle (US 5,814,323) and reference to Farinas et al. cited by applicants on Form PTO-1449 (US 5,906,830) are art of interest.

9. Suggestion: It appears that applicants invention is directed to composition that contains polyvinylpyrrolidone, glycerol monolaurate and lauryl lactate or composition that contains polyvinylpyrrolidone, polysorbate and lauryl lactate. Thus using closed language such as consisting would exclude the other components in the compositions of the prior art.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this

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final Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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